

510(k) SUMMARY: K071026

December 18, 2007

**BD Diagnostics, BD GeneOhm™ StaphSR Assay
Positive Blood Culture Indication**

Submitted by: BD Diagnostics (GeneOhm Sciences Canada Inc.)
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Contact (US Agent): Raymond Boulé
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BD Diagnostics – GeneOhm
6146 Nancy Ridge Drive
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DEC 20 2007

Name of Device:

Trade Name: BD GeneOhm™ StaphSR Assay
Common Name: *Staphylococcus aureus* and Methicillin-resistant
Staphylococcus aureus detection assay
Classification Name: System, Test, Genotypic Detection, resistant and non-
resistant markers, *Staphylococcus* colonies

Predicate Device:

Performance:

Remel Staphaurex Latex Agglutination Test (K851949)
BBL (BD) Oxacillin Screen Agar (K863821)
BD Phoenix Automated ID/AST System (K020322,
K023301)

Technology:

GeneOhm Sciences Canada BD GeneOhm™ MRSA Assay
(K042357)

Device Description:

Intended Use:

The BD GeneOhm™ StaphSR Assay is a qualitative *in vitro* diagnostic test for the rapid detection of *Staphylococcus aureus* (SA) and methicillin-resistant *Staphylococcus aureus* (MRSA) directly from positive blood culture. The assay utilizes polymerase chain reaction (PCR) for the amplification of specific targets and fluorogenic target-specific hybridization probes for the real-time detection of the amplified DNA. The assay is performed on Gram positive cocci, identified by Gram stain, from positive blood cultures. The BD GeneOhm™ StaphSR Assay is not intended to monitor treatment for MRSA/SA infections. Subculturing of positive blood cultures is necessary for further susceptibility testing.

Test Description:

To test a positive blood culture, an aliquot of the culture media is transferred into a sample buffer tube and lysed. Following specimen lysis, amplification of the targets [MRSA: a *S. aureus* specific target and a sequence near the insertion site of the Staphylococcal Cassette Chromosome *mec* (SCC*mec*); SA: another *S. aureus* specific sequence] occurs in the presence of either or both targets. Amplification of the IC, a DNA fragment of 335-bp including a 277-bp sequence not found in *S. aureus* or MRSA, also takes place unless PCR inhibitory substances are present.

The amplified DNA targets are detected with molecular beacon probes, hairpin-forming single-stranded oligonucleotides labelled at one end with a quencher and at the other end with a fluorescent reporter dye (fluorophore). In the absence of target, the fluorescence is quenched. In the presence of target, the hairpin structure opens upon beacon/target hybridization, resulting in emission of fluorescence. For the detection of MRSA amplicon, the molecular beacon probe contains the fluorophore FAM at the 5' end and the non-fluorescent quencher moiety DABCYL at the opposite end of the oligonucleotide. For the detection of *S. aureus* amplicon, the molecular beacon probe is labelled with the fluorophore TexasRed at the 5' end and the quencher DABCYL at the 3' end. For the detection of the IC amplicon, the molecular beacon probe contains the fluorophore TET at the 5' end and the quencher DABCYL at the 3' end. Each beacon-target hybrid fluoresces at a wavelength characteristic of the fluorophore used in the particular molecular beacon probe. The amount of fluorescence at any given cycle, or following cycling, depends on the amount of specific amplicon present at that time. The SmartCycler software simultaneously monitors the fluorescence emitted by each beacon probe, interprets all data, and provides a final result at the end of the cycling program.

Substantial Equivalence:

The BD Diagnostics BD GeneOhm™ StaphSR Assay is substantially equivalent in technology to the currently marketed GeneOhm Sciences Canada BD GeneOhm™ MRSA Assay (K042357). The BD GeneOhm™ StaphSR Assay contains additional primers and molecular beacon probes to detect *Staphylococcus aureus*.

The GeneOhm BD GeneOhm™ StaphSR Assay is substantially equivalent in performance to the Remel Staphaurex Latex Agglutination Test (K851949) for detection of *Staphylococcus aureus*; the culture medium BBL (BD) Oxacillin Screen Agar (K863821) for detection of methicillin-resistant *Staphylococcus aureus*; and the BD Phoenix Automated ID/AST System (K020322, K023301) for detection of both *Staphylococcus aureus* and methicillin-resistant *Staphylococcus aureus*. These methods were used as the reference methods in the clinical trials.

Clinical trials were performed at five sites to evaluate the performance of the BD GeneOhm™ StaphSR Assay. The results are summarized in Tables 1-5:

Table 1. Results obtained with BD GeneOhm™ StaphSR for MRSA and *S. aureus* in comparison to the reference methods

MRSA				<i>S. aureus</i>			
Site 1				Site 1			
Culture/ID-AST System 1				Culture/ID-AST System 1			
BD GeneOhm™ StaphSR		+	-	BD GeneOhm™ StaphSR		+	-
	+	61	5		+	99	0
	-	0	380		-	0	347
		61	385			99	347
			446				446
Site 2				Site 2			
Culture/ID-AST System 2				Culture/ID-AST System 2			
BD GeneOhm™ StaphSR		+	-	BD GeneOhm™ StaphSR		+	-
	+	24	2		+	40	1
	-	0	107		-	0	92
		24	109			40	93
			133				133
Site 3				Site 3			
Culture/Oxacillin Screen Agar				Culture/Oxacillin Screen Agar			
BD GeneOhm™ StaphSR		+	-	BD GeneOhm™ StaphSR		+	-
	+	21	0		+	83	0
	-	0	211		-	0	149
		21	211			83	149
			232				232
Site 4				Site 4			
Culture/ID-AST System 3				Culture/ID-AST System 3			
BD GeneOhm™ StaphSR		+	-	BD GeneOhm™ StaphSR		+	-
	+	48	4		+	84	7
	-	0	234		-	1	194
		48	238			85	201
			286				286
Site 5				Site 5			
Culture/PBP2' Latex				Culture/PBP2' Latex			
BD GeneOhm™ StaphSR		+	-	BD GeneOhm™ StaphSR		+	-
	+	2	0		+	8	0
	-	0	84		-	0	78
		2	84			8	78
			86				86

Table 2. Performance obtained with BD GeneOhm™ StaphSR for MRSA (by investigational site) in comparison to the reference method.

Site	MRSA prevalence	MRSA Positive % Agreement (95% CI) ¹	MRSA Negative % Agreement (95% CI) ¹	Overall % Agreement
Site 1	13.7% (61/446)	100% (61/61) (94.1%-100%)	98.7% (380/385) (97.0% - 99.6%)	98.9%
Site 2	18.0% (24/133)	100% (24/24) (85.8%-100%)	98.2% (107/109) (93.5% - 99.8%)	98.5%
Site 3	9.1% (21/232)	100% (21/21) (83.9%-100%)	100.0% (211/211) (98.3% - 100.0%)	100%
Site 4	16.8% (48/286)	100% (48/48) (92.6%-100%)	98.3% (234/238) (95.8% - 99.5%)	98.6%
Site 5	2.3% (2/86)	100% (2/2) (15.8%-100%)	100.0% (84/84) (95.7% - 100.0%)	100%

¹ Binomial 95% exact confidence intervals.

Table 3. Performance obtained with BD GeneOhm™ StaphSR for *S. aureus* (by investigational site) in comparison to the reference method.

Investigational site	<i>S. aureus</i> prevalence	<i>S. aureus</i> Positive % Agreement (95% CI) ¹	<i>S. aureus</i> Negative % Agreement (95% CI) ¹	Overall % Agreement
Site 1	22.2% (99/446)	100.0% (99/99) (96.3%-100%)	100% (347/347) (98.9%-100%)	100%
Site 2	30.1% (40/133)	100% (40/40) (91.2%-100%)	98.9% (92/93) (94.2%-100%)	99.2%
Site 3	35.8% (83/232)	100% (83/83) (95.7%-100%)	100% (149/149) (97.6%-100%)	100%
Site 4	29.7% (85/286)	98.8% (84/85) (93.6% - 100.0%)	96.5% (194/201) (93.0% - 98.6%)	97.2%
Site 5	9.3% (8/86)	100% (8/8) (63.1% - 100.0%)	100% (78/78) (95.4%-100%)	100%

¹ Binomial 95% exact confidence intervals.

Table 4. Unresolved results

Investigational site	% Initial Unresolved with 95% exact confidence intervals		% Repeat Unresolved with 95% exact confidence intervals	
Site 1	0.0% (0/446)	(0.0% - 0.8%)	0.0% (0/446)	(0.0% - 0.8%)
Site 2	0.0% (0/133)	(0.0% - 2.7%)	0.0% (0/133)	(0.0% - 2.7%)
Site 3	0.0% (0/232)	(0.0% - 1.6%)	0.0% (0/232)	(0.0% - 1.6%)
Site 4	0.3% (1/286)	(0.0% - 1.9%)	0.0% (1/286)	(0.0% - 1.3%)
Site 5	0.0% (0/86)	(0.0% - 4.2%)	0.0% (0/86)	(0.0% - 4.2%)

Table 5. Invalid assays

Investigational site	% Initial invalid runs with 95% exact confidence intervals		% Invalid repeat runs with 95% exact confidence intervals	
Site 1	1.8% (2/113)	(0.2% - 6.2%)	0.0% (0/113)	(0.0% - 3.2%)
Site 2	8.9% (5/56)	(3.0% - 19.6%)	0.0% (0/56)	(0.0% - 6.4%)
Site 3	2.9% (2/69)	(0.4% - 10.1%)	0.0% (0/69)	(0.0% - 5.2%)
Site 4	2.4% (2/84)	(0.3% - 8.3%)	0.0% (0/84)	(0.0% - 4.3%)
Site 5	7.7% (5/65)	(2.5% - 17.0%)	0.0% (0/65)	(0.0% - 5.5%)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 20 2007

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Raymond Boulé
Senior Director, Regulatory Affairs
BD Diagnostics (GeneOhm Sciences Canada, Inc.)
6146 Nancy Ridge Drive
San Diego, CA 92121

Re: K071026
Trade/Device Name: BD GeneOhm™ StaphSR Assay
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: NQX
Dated: November 23, 2007
Received: November 26, 2007

Dear Mr. Boulé:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

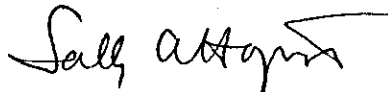
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K071026

Device Name: BD GeneOhm™ StaphSR Assay

Indications For Use:

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Prescription Use _____XXX_____ OR

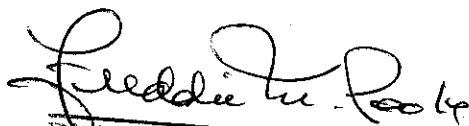
(Per 21 CFR 801.109)

Over-The-Counter Use

(Optional Format 1-2-96)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices Evaluation and Safety (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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